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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,354	09/08/2003	Joanna Graft	480062002500	1649

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EXAMINER	
CARPENTER, WILLIAM R	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,354	GRAFT ET AL.	
	Examiner	Art Unit	
	WILLIAM CARPENTER	4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-5, 8, 10, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 7,077,597 ("Davies").

As regards to Claim 1, Davies teaches a device comprising a body (1) having a proximal end (Figure 1, the end at the bottom of the page) and a distal end (Figure 1, the end at the top of the page). The body comprises a first opening (5) and a second opening (2, 3, or 4) spaced apart by a distance sufficient to ensure the separation of the two distal tip sections of a split-tip catheter. Davies further discloses that the body is bendable as seen in Figure 2. While Davies does not teach his device in use with a split-tip catheter the mention of a split-tip catheter is only an intended use, not a positive limitation. All that is required is that the device of Davies has the ability to function as a split tip

catheter divider. Clearly, the device of Davies is capable of functioning as such as a result of the structural similarities to the device claimed by Applicant.

As regards to Claim 2, Davies does not explicitly indicate the distance between the first and second openings. However, we are able to reasonably infer the distance based on the geometry of a standard three-ring binder. Given the size of a three ring binder and the use of either 13 or 14 inch long legal paper (Column 1, Lines 25-27) the distance between the first and second opening could be as long as approximately 11 inches (Figure 1, the distance between openings 5 and 2) or a short as approximately 2 inches (Figure 1, the distance between openings 5 and 4). These values are derived using a standard spacing of 4.5 inches between the rings of the binder and a spacing of 1 inch between the edge of the page and the 1st and 3rd rings. Page 6, Lines 5-7 of Applicant's disclosure states that one embodiment of the device would have spacing between the two openings of "approximately 2 inches" which would be capable of accommodating both "14.5 Fr and 16 Fr catheters". This distance of approximately 2 inches is assumed to be in compliance with the limitations set forth by Claim 2. As such, the distance of the device of Davies satisfies the limitations by teaching a distance between openings of approximately 2 inches or greater.

As regards to Claim 3, while Davies does not explicitly disclose the size of the disclosed openings ISO 838 specifically governs the diameter of filing holes to be 6 ± 0.5mm, resulting is standard sizing to be between 5.5 mm and 6.0 mm. Applicant discloses split-tip catheters of 14.5 Fr and 16 Fr, which corresponds to diameters of 4.83 mm and 5.33 mm respectively. Accounting for variations in

manufacture, it would be reasonable to expect a tension to be created between a hole of the smallest standard diameter and a catheter of the largest diameter.

As regards to Claim 4, Davies teaches a device that is configured for attachment to a packaging tray. Davies teaches a circular aperture at the distal end (Figure 1, Item 2) that is designed specifically for the purpose of attachment, in the instant case a binding ring of a standard three-hole binder (Figure 2, Item 8). The mention of a packaging tray is not a positive limitation, rather only a configuration for attachment is required. As such, the limitations of Claim 4 are met by Davies.

As regards to Claim 5, Davies teaches the distance between the first opening (Figure 1, Item 5) and the proximal end (Figure 1, the end at the bottom of the page) to be less that the distance between the second opening (Figure 1, Item 3 or 4) and the distal end (Figure 1, the end at the top of the page).

As regards to Claim 8, Davies teaches his device to be 13 or 14 inches from the proximal end to the distal end (Column 1, Lines 25-27).

As regards to Claim 10, Davies teaches his device to incorporate a weakened section between the first and second holes (Figure 1, Item 7). In the instant case, the weakened area is represented by a fold line, which allows legal size paper to be folded such that it will fit in a standards letter sized three-ring binder.

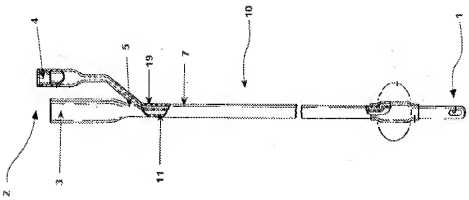
As regards to Claim 11, Davies teaches his device to incorporate a weakened area between the first opening and an edge of the body (Figure 3g,

Item 23). In the instant case this weakened area is represented by a perforated slit that allows the paper to be unfolded without opening the binder rings.

3. Claims 1, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3,379,197 ("Hayes").

As regards to Claims 1, 12, and 13, Hayes discloses a dividing element (24) comprising a bendable body (Column 4, Lines 34-35) having a proximal end (1; See attached figure) and a distal end (2; See attached figure). Hayes discloses the body to be open ended such that its proximal end is penetrable by a syringe (25) and its distal end can receive a tip (4) of a split-tip catheter. Hayes further discloses that the openings are spaced apart by a sufficient length as to ensure that an inner surface of a first tip (3) is separated by an inner surface of a second tip (4). Hayes specifically discloses this dividing element to be used in conjunction with a "split-tip catheter" (10) consistent with Applicant's special definition. In Paragraph 11 of Applicant's specification "split-tip catheter" is explicitly defined as "a catheter having a body enclosing at least two lumens and a dividing point that separates at least two tip sections from one another distal thereto, each of the top sections enclosing at least one lumen and being separated or separable from one another along their length". The catheter of Hayes has a body (7) enclosing two lumen (11 and 19) and a dividing point (5) separating two distal (2) tip sections (3 and 4) each of which enclose one lumen and are separable from one another along their length. In the instant case the term "distal" is afforded its customary definition as "situated away from the point of origin". "Distal" is therefor a product of perspective and in its broadest

reasonable interpretation, either end of the device of Hayes could be considered the "distal end".



Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 3, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 7,077,597 ("Davies") as applied to Claim 1 above, and further in view of WO 03/029020 A1 ("Jung").

As regards to Claims 6 and 7, Davies teaches the limitations of Claim 1, on which Claims 6 and 7 are dependent. What Davies fails to teach is that the first and second openings comprise slits. However, Jung teaches paper and a method for binding it that uses x-shaped slits (Figure 2, Item 21a) as a variant of traditional circular apertures (Figure 3, Item 21b). Jung teaches these variants in the same context of the openings in Davies, binding leaves of paper into an attachment device. It would be obvious to one having ordinary skill in the art to

substitute x-shaped slits for the circular apertures of Davies, as these two types of openings are interchangeable as suggested by Jung.

As regards to Claim 3, should Examiner's argument that one would reasonable expect, due to variance in manufacture, the original holes of the device of Davies would create a tension with an inserted tip of a 16 Fr split-tip catheter not be found persuasive, Claim 3 is alternatively rejected in view of Jung. As disclosed above Jung discloses x-shaped slits to be an obvious variant of traditional circular apertures in the task of binding leaves of paper. As such it would have been obvious for one having ordinary skill in the art to substitute x-shaped slits for the circular apertures of Davies, due to the interchangeability taught by Jung. In doing so, one having ordinary skill in the art would reasonable expect and appreciate that such slits would provide a tension for small cylindrical bodies inserted therethrough, including the individual tip sections of a split-tip catheter.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 7,077,597 ("Davies") as applied to Claim 1 above, and further in view of US Patent No. 5,047,121 ("Kochar").

As regards to Claim 9, Davies teaches the limitations of Claim 1, on which Claim 9 is dependent. What Davies fails to teach is his device to be composed of polyethylene. However, Kochar teaches a synthetic pulp paper product composed of polyethylene (Abstract, Lines 1-4). Polyethylene paper is used as an alternative to wood pulp paper, especially concerning important documents where resistance to degradation and water damage is desired. The device of

Davies is used specifically with legal documents, such as contracts (Column 1, Lines 25-27). It would have been obvious for one having ordinary skill in the art to print the legal documents of Davies on a high-grade polyethylene paper as disclosed by Kochar as to protect against damage and degradation.

20. Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,382,568 ("Snell") in view of US Patent No. 4,925,452 ("Melinyshyn et al.").

As regards to Claim 12, Snell teaches a dividing element for use with medical devices and instruments, particularly tubular devices, in order to keep individual leads separate (Abstract). This dividing element has a body (12 and 16 in combination), a proximal end (See attached figure) and a distal end (See attached figure). Snell further teaches a 1st and 2nd opening (12a and 12b) spaced apart by a sufficient distance to ensure the separation of two tip sections. While Snell discloses that a portion (12) of the body is rigid Snell further discloses that a portion (16) of the body is bendable/flexible (Column 3, Lines 24-26). The broadest reasonable interpretation of the term "bendable" does not necessitate that the body in its entirety is capable of being bent, only that a portion of it is.

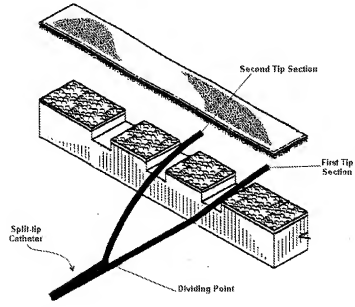
What Snell fails to teach is this device is specifically for use with split-tip catheters. Melinsyhyn et al. provides the specific motivation as to why such a device would be useful with respect to split-tip catheters. Melinyshyn teaches the importance of limiting relative movement of the lumen of a split-tip catheter, specifically during storage, to prevent damage to the catheter lumen. (Column 2,

Lines 56-61). While Melinyshyn targets this concerning by fusing the two lumen with a weakened membrane, one in the art would reasonably recognize and appreciate the device of Snell would function equivalently, to the device as taught by Melinyshyn, preventing relative movement of the distal lead of a split-tip catheter. For this reason, it would have been obvious for one having ordinary skill in the art to insert the distal tips of a split-tip catheter in the openings of Snell as to prevent relative movement.

As regards to Claims 13 and 15, Snell discloses a dividing element for use with medical devices and instruments, particularly tubular devices, in order to keep individual leads separate (Abstract). This dividing element has a body (12 and 16) in combination having a first opening (12a) spaced apart from a second opening (12b). While Snell discloses that a portion (12) of the body is rigid Snell further discloses that portion (16) of the body is bendable/flexible (Column 3, Lines 24-26).

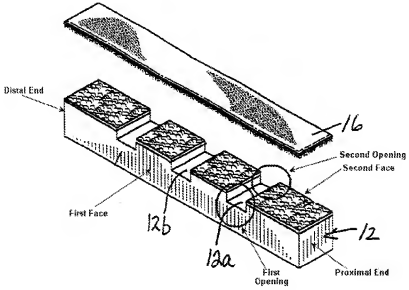
What Snell fails to teach is this device specifically for use with split-tip catheters. Melinsyhyn et al. provides the specific motivation as to why such a device would be useful with respect to split-tip catheters. Melinyshyn teaches the importance of limiting relative movement of the lumen of a split-tip catheter, specifically during storage, to prevent damage to the catheter lumen (Column 2, Lines 56-61). While Melinyshyn targets this concerning by fusing the two lumen with a weakened membrane, one in the art would reasonably recognize and appreciate the device of Snell would function equivalently, to the device as taught by Melinyshyn, preventing relative movement of the distal lead of a split-tip

catheter. For this reason, it would have been obvious for one having ordinary skill in the art to insert the distal tips of a split-tip catheter in the openings of Snell as to prevent relative movement.



As regards to Claim 14, in the instant case the device of Snell is interpreted such that the first opening comprises the opening in the first face (See attached figure) defining through going channel (12a) while the second opening comprises the opening in the second face (See attached figure) further defining through going channel (12a) when the base (12) and the strap (16) are unified in a single structure. Such an interpretation is believed to be within confines of the broadest reasonable interpretation of the term "opening". Given this interpretation when the first or second tip of the catheter is inserted into channel (12a) it will be received by both the first and second openings. The reinterpretation of what constitutes the openings of the device of Snell is not

believed to affect the properness of the combination of Melinyshan as the first tip is still intended to be inserted within channel (12a) and the second tip is still intended to be inserted within channel (12b).



As regards to Claim 16, when a first tip section is inserted through channel (12a) and the second tip section is inserted through channel (12b) the dividing element will be interposed between and extending along a longitudinal length of the first and second tip sections.

As regards to Claim 17, the device of Snell is selectively detachable from a split-tip catheter inserted therein by either removing strap (16) or withdrawing the tip sections from their respective channels.

As regards to Claim 18, Melinyshyn specifically discloses prohibiting relative movement of the catheter during storage (Column 2, Lines 56-61). Furthermore, it is believed to be inherent that the split-tip catheter would have to

be removed from the storage device of Snell before the tip sections could be inserted into a patient's blood vessels.

Response to Arguments

7. Applicant's arguments filed 12/04/2007 have been fully considered but they are not persuasive.

8. In response to applicant's argument that the device of Davies is not configured for use with a split-tip catheter, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As Applicant has submitted no evidence that the device of Davies would not be suitable for satisfying the intended use, and numerous structural similarities have been presented above, it is believed to be clear that the device of Davies is capable of acting as a dividing element for a split-tip catheter.

9. In response to applicant's arguments, the recitation of a "split-tip catheter" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.

See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Furthermore the addition of the language "of the split-tip catheter" into the body of independent Claim 1 does not serve to require a split-tip catheter as a necessary part of the work-piece. Rather it is only referential to the preamble and to an intended use of the claimed invention. As the device of Davies discloses all of the structure required by the limitations of Claim 1 and possesses numerous structural similarities to the disclosed device as a whole, it is believed that the device of Davies is capable of functioning as a split-tip catheter divider should one be so inclined. Should Examiner's argument that the added language in the body of the claim fails to impart any additional structure not found in Davies or positively requires a split-tip catheter to be part of the work piece not be found persuasive Claim 1 is alternatively rejected as being anticipated by Hayes in Paragraph 3 above.

10. In response to Applicant's argument that the device of Snell does not comprise a "bendable body" as claimed. While Snell does disclose that a portion (12) of the body of the device is a "rigid tube and wire separation block 12", Snell further discloses that a portion (16) of the body of the device is a "**flexible** elongated hook/loop strap 16" (Column 3, Line 23). In order to satisfy the broadest reasonable interpretation of the term "bendable body" the entirety of the disclosed body need not be capable of being bent, only a portion. As the body of the device of Snell has been consistently referred to as "12 and 16 in combination", the body is not merely the rigid block as claimed by Applicant, but

rather the rigid block (12) *and* the *flexible* strap (16). Should Examiner's argument that the phrase "bendable body" necessitates the body in its entirety be capable of flexion Claims 1, 12, and 13 are rejected as being anticipated by Hayes in Paragraph 3 above.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

WC
2/1/2008

/Sam Chuan C. Yao/

Supervisory Patent Examiner, Art Unit 4111